NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

Civil Action No. 02-3779(JWB)

O P I N I O N

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BISSELL, Chief Judge

This matter comes before the Court on motions in limine made by Plaintiff SmithKline Beecham Corp. ("SKB") and Defendant Teva Pharmaceuticals USA, Inc. ("Teva"). This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1338.

FACTS AND BACKGROUND[1]

Plaintiff filed a patent infringement suit to protect its rights under U.S. Patent 4,602,017 (the "'017 patent") which is sold by plaintiff under the trade name Lamictal®. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") filed Abbreviated New Drug Applications ("ANDA") with the Food and Drug Administration ("FDA") seeking approval to market generic versions of the product covered by the '017 patent. Teva alleged in its Paragraph IV certification that every claim except claim 5 of the

[1] A complete recitation of the facts of this case can be found in this Court's March 5, 2003 Opinion. This Opinion will recite those general facts which are relevant to the instant motion.

'017 patent is either invalid or would not be infringed by the commercial manufacture, use or sale of the product covered in the ANDAs. Teva alleged, inter alia, that the '017 patent was invalid because SKB engaged in inequitable conduct. After receiving Teva's Paragraph IV notices, SKB timely filed separate infringement actions against Teva. The cases were consolidated by this Court on November 27, 2002. On July 15, 2004, this Court granted SKB's summary judgment motion of no inequitable conduct.

The motions in limine which are presently before this Court include (1) Teva's motion to preclude evidence of objective considerations of non-obviousness as irrelevant under Federal Rules of Evidence 401-403; (2) SKB's motion to preclude the testimony by Teva's trial experts on patents and publications not discussed in the body of their expert reports, or in the alternative, to compel additional discovery; and (3) SKB's motion to preclude testimony by Dr. Harvey Kupferberg based on "unproduced data."

DISCUSSION

I. Preclusion of Evidence Relating to Objective Considerations

Title 35 U.S.C. § 101 precludes more than one patent on the same invention if the subject matter is identical to an earlier patent. See 35 U.S.C. § 101 (2000); see also Geneva Pharma., Inc. v. Glaxosmithkline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003). To combat this statutory requirement, applicants may

draft claims that have slight variations from the earlier patent. Id. To prevent the issuance of a patent on claims that are nearly identical to claims in an earlier patent, the United States Court of Customs and Patent Appeals[2] drafted a doctrine of nonstatutory double patenting. See Geneva Pharma., at 1377-78. This doctrine, which is also known as "obviousness-type" double patenting, "prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant." Id; see also Eli Lilly and Co., v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001).[3] Obviousness-type double patenting is "judicially created and prohibits an inventor from obtaining a second patent for claims that are not patentably distinct from the claims of the first patent." In re Lonardo, 119 F.3d 960, 965 (Fed. Cir. 1997).

There are two steps in an obviousness-type double patenting analysis. See Eli Lilly, at 968. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in

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[2] The United States Court of Customs and Patent Appeals is the predecessor of the U.S. Court of Appeals for the Federal Circuit.

[3] There are two types of double patenting, "same invention" double patenting and "obviousness-type" double patenting. Same invention double patenting, which is based on 35 U.S.C. § 101, "states that an inventor may obtain 'a patent' for an invention." In re Lonardo, 119 F.3d 960, 965 (Fed.Cir. 1997). This statute therefore "permits only one patent to be obtained for a single invention, and the phrase 'same invention' refers to an invention drawn to substantially identical subject matter." Id.

the later patent and determines the differences." Id. (citing Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999)). The second step is then for the Court to determine "whether the differences in subject matter between the two claims render the claims patentably distinct." Eli Lilly, at 968; Georgia-Pacific, at 1327. Thus, it is possible that when analyzing an obviousness-type double patenting issue, "a rejection may be applied to clearly distinct inventions." In re Longi, 759 F.2d 887, 893 (Fed. Cir. 1985) (internal citations omitted).

When describing the distinctions between obviousness under 35 U.S.C. § 103 and nonstatutory double patenting, the Federal Circuit Court stated the following:

> 1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
>
> 2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
>
> 3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

See Geneva Pharma., at 1378, n.1.

The Manual of Patent Examining Procedure, however, suggests that secondary considerations be used to determine whether a nonstatutory basis exists for a double patenting rejection. See

M.P.E.P. § 804 (II)(B)(1). Section 804 states that "any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination." Id. (citing In re Braat, 937 F.2d 589, 592-93 (Fed. Cir. 1991) ("this court has endorsed an obviousness determination similar to, but not necessarily the same as, that undertaken under 35 U.S.C. § 103 in determining the propriety of a rejection for double patenting"); In re Longi, 759 F.2d 887 (Fed. Cir. 1985)). Therefore, according to the manual, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1 (1966), are applicable when making an obviousness-type double patenting analysis. See M.P.E.P. § 804 (II)(B)(1). Such considerations include any objective indicia of non-obviousness. Id.

In order to attack Teva's obviousness-type double patenting defense, SKB seeks to rely upon secondary considerations of non-obviousness. Such secondary considerations are also known as "objective indicia", "objective considerations" or "objective criteria." The evidence which SKB seeks to submit includes that which represents the alleged commercial success of the invention and the acquiescence by others in the field in contesting the validity of the patent. Specifically, SKB seeks to introduce evidence of 1) the commercial success of lamotrigine in the treatment of epilepsy and 2) the fact that "the other three

generic drug makers seeking to market lamotrigine have not even attempted to challenge the validity of SKB's patent." See SKB Opp'n at 1.

Although only addressed in a footnote, the Geneva Court has set forth the most recent and the most direct guidance on the use of secondary considerations in the context of a double patenting analysis. See Geneva Pharma., at 1378, n.1. In reviewing the cases cited by SKB and the treatment of this issue by the Federal Circuit, this Court does not join in SKB's conclusion that "unless objective indicia are considered, the conclusion of obviousness-type double patenting cannot be reached." See SKB Opp'n at 3. The Court's role in analyzing an obviousness-type double patenting issue is clear. First, the claims of the earlier and later patents must be construed and then compared. See Eli Lilly and Co, v. Barr Labs., Inc., 251 F.3d 955, 968 (Fed. Cir. 2001). Once this has been done, the Court must then identify the differences and distinctions, if any, between the two patents. Id. This double patenting analysis does not require, nor does it invite, the consideration of so called objective indicia.[4] Furthermore, the Federal Circuit has made it quite clear that a "double patenting [analysis] depends entirely on what is claimed in an issued patent." Therefore, because this

[4] Frankly, the evidence which SKB seeks to introduce has several subjective components such as decisions in the market place the motivation for which cannot be easily determined.

Court finds that the double patenting analysis will draw completely from the patents at issue, it will preclude SKB from introducing evidence of secondary considerations.

The Court next turns to the admissibility of evidence of unexpected properties. Without commenting on whether evidence of unexpected properties is a primary or a secondary consideration, this Court determines that SKB is correct in arguing that a compound and its properties are inseparable. See In re Papesch, 315 F.2d 381, 391 ("... a compound and its properties are inseparable; they are one and the same thing."). Therefore, to the extent that SKB seeks to introduce the biological properties of Lamotrigine, it is free to do so.

II. Preclusion of Testimony by Defendant's Trial Experts

Pursuant to Federal Rule of Civil Procedure 37(b)(2)(B), a District Court can sanction a party's failure to comply with a discovery order by "prohibiting that party from introducing designated matters into evidence." See Fed. R. Civ. P. 37(b)(2)(B); see also In re TMI Litig., 193 F.3d 613, 721 (3d Cir. 1999). In evaluating whether the District Court properly exercised its discretion, the Third Circuit will consider the following factors:

> (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified,

(2) the ability of that party to cure the prejudice,

(3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and

(4) bad faith or willfulness in failing to comply with the district court's order.

See In re TMI Litig., at 721 (citing Semper v. Santos, 845 F.2d 1233, 1237 (3d Cir. 1988); Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894 (3d Cir. 1977)).

A. Testimony by Teva's Experts on Information Not Contained Within the Expert Reports

SKB claims that Teva has stated that the patents and publications on which it intends to rely can be found among a large number of sources, such as its trial exhibit list. SKB argues that the inclusion of this material by Teva is a direct violation of this Court's case management orders under Fed. R. Civ. P. 16 and the expert disclosure requirements of Fed. R. Civ. P. 26 because the numerous patents and publications were never addressed in the various reports of Teva's trial experts. SKB claims that it has been prejudiced by Teva's conduct, because it cannot adequately prepare for trial without knowing what patents and publications Teva intends to use at trial. SKB requests that this Court preclude the testimony by Teva's trial experts on patents and publications not discussed in the previously filed

reports. In the alternative, SKB requests that Teva be compelled to provide discovery on the relevant patents and publications.

Contrary to SKB's allegations, Teva claims that its "two experts have prepared and submitted comprehensive expert reports, which describe, inter alia, their qualifications, compensation, prior work experience, publications and opinions regarding the patent in suit along with a list of all materials that each considered and on which they intend to base their testimony." Teva Experts Opp'n at 1. Teva submits that its experts intend to testify at trial according to what is set forth in their expert reports and what was covered during their depositions. Id. at 2.

Upon review of the information contained within the Final Pretrial Order, this Court does not find any validity in SKB's conclusion that Teva intends to use its trial experts in a manner other than that which was included in their respective expert reports. Accordingly, SKB's motion to preclude the testimony of Teva's experts is denied. If, at trial, Teva seeks to introduce evidence which is beyond the scope of its experts' reports or evidence which was not explored during the depositions of Teva's experts, this Court will then make a determination of the admissibility of such evidence.

B. Testimony of Dr. Harvey Kupferberg

SKB also seeks to preclude the testimony of Dr. Harvey

Kupferberg which relates to confidential data from third parties to which the Doctor had access during his employment at the National Institutes of Health. SKB Kupferberg Br. at 1. SKB claims that Dr. Kupferberg failed to disclose this information in his expert report or during the course of his deposition. Id. From 1975 to 2000, Dr. Kupferberg directed the preclinical component of the National Institute of Neurological Disorders and Stroke ("NINDS") at the National Institutes of Health in Bethesda, Maryland. See Opening Expert Report of Harvey J. Kupferberg, Ph.D., Pharm. D. ("Kupferberg Report") ¶ 4, Attached to Final Pretrial Order, Vol. III, Ex. 7. During that time, Dr. Kupferberg also served as the Project Officer for the Anticonvulsant Screen Project ("ASP") at the University of Utah. The ASP was responsible for the evaluation of over 24,000 new chemical entities for their antiepileptic potential. Id.

During his deposition, Dr. Kupferberg testified that he had entered into a confidentiality agreement with the National Institutes of Health and that agreement precluded him from commenting on specific compounds for which data was acquired as part of the ASP. See SKB Kupferberg Br. at 2; see also Teva Kupferberg Opp'n at 2; Deposition Testimony of Dr. Kupferberg, Attached to Declaration of Christopher E. Loh, Esq., Ex. 12. However, Dr. Kupferberg stated that he was permitted to "summarize the data in such a way" so as to not "break

confidentiality of what compound and who sent it." Furthermore, Dr. Kupferberg testified that his "general experience" at the National Institutes of Health "is not confidential." See Deposition Testimony of Dr. Kupferberg, at 296:5-21 & 343:2-6, Attached to Declaration of Robert J. Fettweis, Esq., Ex. F.

SKB argues that this Court should not allow Dr. Kupferberg to testify at trial about the ASP data, or to base any opinion on that data, because he failed to include the information in his expert report. SKB claims that this failure amounts to a violation of Teva's expert discovery obligations. SKB seeks the partial preclusion of Dr. Kupferberg's testimony under the Federal Rules of Civil Procedure 26 and 37.

Federal Rule of Civil Procedure 26(a)(2)(B) states that a witness who is employed to provide expert testimony shall prepare and sign a written report which is to include:

> ... a complete statement of all opinions to be expressed and the basis and reasons therefor; the data or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years.

Federal Rule of Evidence 705 also governs the disclosure of

information by expert witnesses and it states:

> The expert may testify in terms of opinion or inference and give reasons therefor without first testifying to the underlying facts or data, unless the court requires otherwise. The expert may in any event be required to disclose the underlying facts or data on cross-examination.

Fed. R. Evid. 705.

Rule 705 governs the timing of the disclosure of information testified to by experts. However, the Federal Rules do not require any disclosure to be made for information that is not relied upon by the expert. Teva claims that Dr. Kupferberg "has never indicated that his expert opinions were based on any of the specific ASP data. Instead, they were based on the public summary information." See Teva Kupferberg Opp'n at 3; see also Kupferberg Dep., 296:17-21 ("I can take the data and summarize the data in such a way that I don't break confidentiality of what compound and who sent it."). However, in his expert report, Dr. Kupferberg included the following:

> Based on my experience in reviewing the ASP data of over 24,000 potential anticonvulsant compounds, in my opinion the difference in ED_{50} values for lamotrigine and its 2-chlorophenyl analogue does not indicate that lamotrigine is a superior anticonvulsant compared to its 2-chlorophenyl analogue.

See Kupferberg Expert Report, ¶ 76.

Thus, it is evident that although Dr. Kupferberg may be able

to summarize the data in such a way so as not to break confidentiality, the basis for his opinion (at least with respect to Paragraph 76 of his expert report) was at least partially related to the confidential ASP compound data. Therefore, this Court must assess whether to preclude this testimony.

The first two factors which must be considered are the "prejudice or surprise in fact of the party against whom the excluded witnesses would have testified" and the ability of that party to cure the prejudice. See In re TMI Litig., 193 F.3d 613, 721 (3d Cir. 1999). SKB argues that it would be prejudiced by the inclusion of this opinion testimony because it would not have the ability to adequately cross-examine Dr. Kupferberg about his opinion at trial. This Court agrees with SKB. If the entirety of Dr. Kupferberg's testimony related only to his general experience, then the prejudice would not be nearly as great. However, Teva has submitted Dr. Kupferberg's expert report, which specifically refers to that information which Dr. Kupferberg claims to be covered by the confidentiality agreement. Thus, not allowing SKB access to information which forms the basis of this opinion would severely prejudice SKB. Furthermore, any harm to Teva is minimal as this Court does not intend to preclude the entirety of Dr. Kupferberg's testimony.[5]

[5] Teva relies upon Fitz, Inc. v. Ralph Wilson Plastics Co., 184 F.R.D. 532 (D.N.J. 1999) to support its position that Dr. Kupferberg has provided a complete statement of his opinions. In

The third consideration in this analysis is "the extent to which waiver of the rule ... would disrupt the orderly and efficient trial of the case or of other cases in the court." Id. To allow this testimony would not necessarily disrupt the orderly and efficient trial of the case. However, for the reasons stated above, by allowing this testimony, this Court would be placing SKB at a definite disadvantage. Finally, the fourth factor, looks to any "bad faith or willfulness in failing to comply with the district court's order." Id. While this Court can find no signs of bad faith or willfulness on the part of Teva, the impact of the other factors discussed herein, weighs in favor of the exclusion of this portion of Dr. Kupferberg's testimony. Accordingly, this Court will exclude any and all testimony which relies upon the actual compounds and any other relevant information which, because of confidentiality restrictions, was undisclosed to SKB.

Fitz, Magistrate Judge Rosen determined that despite the fact that plaintiff's expert did not disclose confidential formulas or testing procedures, he had provided substantial information concerning the basis of his opinion. Id. at 538. In the case at bar, while Dr. Kupferberg does provide substantial information concerning the basis of his opinion, he opines that the difference he observes in the ED_{50} values is based on his "experience in reviewing the ASP data of over 24,000 potential anticonvulsant compounds." See Kupferberg Expert Report, ¶ 76. Thus, effective cross-examination of Dr. Kupferberg might require an assessment of the anticonvulsant compounds which were reviewed by him at ASP, and which he has not disclosed. The Court will not create this dilemma.

CONCLUSION

For the foregoing reasons, SKB's motion in limine to preclude the testimony by Teva's trial experts on patents and publications not discussed in the body of their expert reports, or in the alternative, to compel additional discovery is denied. SKB's motion to preclude testimony by Dr. Harvey Kupferberg based on confidential data which has not been produced is granted. Finally, Teva's motion to preclude evidence of objective considerations of non-obviousness as irrelevant under Federal Rules of Evidence 401-403 is granted.

/s/ John W. Bissell
JOHN W. BISSELL
Chief Judge
United States District Court

DATED: January 13, 2005